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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/511,911

08/18/2005

Ib Joergensen

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4306

57360

7590

06/12/2009

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EXAMINER

CAMPBELL, VICTORIA P

ART UNIT

PAPER NUMBER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/511,911	Applicant(s) JOERGENSEN ET AL.	
	Examiner VICTORIA P. CAMPBELL	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,13 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-8,13 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/31/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the second Office Action following the Request for Continued Examination based on the 10/511911 application filed August 18, 2005. Claims 1, 4-8, 13, and 21-33 as amended March 23, 2009 are currently pending and considered below.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor

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and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4-8, 21, 22, 24, 25, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPN 4,960,410 to Pinchuk in view of USPGPub 2002/0072730 A1 to McGill et al.

Regarding the above claims, Pinchuk discloses a balloon catheter comprising a catheter shaft having a distal end (24), an inflatable balloon disposed on the distal end (12), a proximal end coupled to a connecting piece (30), a guiding wire lumen (22), and an inflation lumen (52). Pinchuk further discloses that the guiding wire lumen has coupled proximal (60) and distal (64) portions wherein the proximal portion is made of a more rigid metallic material and the distal portion is made of a less rigid plastic material (Col. 3, line 65-Col. 4, line 11). However, Pinchuk fails to explicitly teach or disclose that a transitional portion is provided with kink protection at least partially overlapping the proximal and distal portions. However, McGill et al teach a kink protection portion (205) which extends over both a proximal and distal portion. They further teach a second form a kink protection in the form of a metal coil (634), which the examiner believes could be placed inside or outside of the pipe.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter of Pinchuk with the kink

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protection sleeve or metal coil of McGill et al in order to provide increased stability in the catheter when navigating tortuous regions.

5. Claims 13, 23, 26, 27, 30, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk and McGill et al as applied to claims 4, 21, and 24 above, and further in view of USPN 5,951,494 to Wang et al.

Pinchuk and McGill et al disclose all of the limitations of claims 4, 21, and 24 as described above, but do not appear to explicitly disclose a lubricity enhancing coating on the inner surface of the guidewire lumen. However, Wang et al disclose coating the interior of a catheter lumen with a tube of TEFLON (Col. 16, lines 60-64), which can extend for any length of the tube. Pinchuk, McGill et al, and Wang et al are analogous art because they are from the same field of endeavor/problem solving area of catheters. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Pinchuk, McGill et al, and Wang et al before him or her to modify the interior lumen of Pinchuk and McGill et al to include the coating of Wang et al because doing so can help facilitate the introduction of a guidewire through the lumen (Wang et al, Col. 16, lines 62-64). Therefore, it would have been obvious to combine Pinchuk and McGill et al with Wang et al to obtain the invention in the instant claims.

6. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, McGill et al, and Wang et al as applied to claim 27 above, and further in view of USPGPub 2003/0050600 A1 to Ressemann et al.

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Ressemann et al further teach the limitation of plasma treating for increasing adherence, which the examiner asserts would be possible to do on either the interior of the catheter or the exterior of the plastic tubing. The examiner further asserts that this process renders the plastic tubing adherent, thereby making the outer layer adhesive. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the coating techniques of Ressemann et al with the catheter as stated above in order to ensure good adhesion of the friction-reducing interior polymeric layer.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk and McGill et al as applied to claim 1 above, and further in view of USPN 6,596,217 B1 to Davis-Lemessy et al.

Davis-Lemessy et al teach the use of a nylon tube in the construction of a catheter (Col. 4, lines 15-40), which is not taught by either Pinchuk or McGill et al. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the nylon tube construction of Davis-Lemessy et al in order to be able to fusion bond with nylon balloons (Col. 4, lines 15-40).

Response to Arguments

8. Applicant's arguments filed March 23, 2009 have been fully considered but they are not persuasive.

9. Regarding applicant's argument that McGill et al do not teach a kink protection sleeve that overlaps both the proximal and distal portions of the tube, the examiner disagrees and directs applicant's attention to tube 205 in figures 16-

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19. The examiner notes that in both the embodiment of Figures 16 and 17 and the embodiment of Figures 18 and 19, the tube 205 extends over portions of both the proximal and distal portions.

10. Regarding applicant's argument that McGill et al's metal coil does not traverse both the proximal and distal portions, the examiner notes that she was not relying upon the particular coil of McGill et al to teach a coil which traverses both the proximal and distal portions, she was simply relying on the teaching of McGill et al that a coil can be used for kink protection, after already teaching one form of kink protection which does traverse both the proximal and distal portions.

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the examiner notes that increased resistance to kinking is often desirable in tubular medical articles and therefore the aforementioned increase in resistance to kinking at a particular location known to be susceptible to kinking would be sufficient reason to combine the two methods of kink resistance as presented by Pinchuk and McGill et al.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Victoria P Campbell
Examiner, AU 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763